

Patent *16276*
Attorney's Docket No. 003300-883 *DFV*

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of)	
Leif Lindholm)	Group Art Unit: 1636
Application No.: 10/019,566)	Examiner: Maria Marvich, Ph.D.
Filed: March 28, 2002)	Confirmation No.: 8060
For: RECOMBINANT ADENOVIRUS)	

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In complete and timely response to the Office Action of September 17, 2004, Applicant submits the following response. A Petition for a one-month extension of time extending the period for response from October 17, 2004 to November 17, 2004 is attached hereto.

Election of Group I

In the Office Action, the Examiner sets forth a restriction requirement among two groups of the claims. Group I (Claims 1-21 and 23) is "drawn to a recombinant adenovirus with changed tropism and use of the recombinant adenovirus for treatment of disease in vivo and method of producing the recombinant adenovirus." Group II (Claim 22) is "drawn to a use of the recombinant adenovirus for the treatment of human disease by in vitro methods."

Applicant elects Group I, Claims 1-21 and 23 *without traverse*.

Election of a Single Sequence

Regarding election of a specific sequence, Applicant *traverses* the restriction requiring election of a single sequence. Under M.P.E.P. § 803, a restriction is proper if the subject matter can be restricted into one or two or more claimed inventions, and these inventions are either independent (M.P.E.P. § 806.04) or distinct

(M.P.E.P. § 806.05). However, the second element for a restriction requirement to be proper is that if the search and examination of an entire application can be made without serious burden, the examiner *must* examine the application on the merits, even though it includes claims to independent and distinct inventions. Additionally, the instant application is a national phase application of an International PCT Application. Restriction practice under 35 U.S.C. § 121 and its associated rules do not apply. The Examiner reviewing the PCT application did not require restriction of the claims based on one specific sequence. Nor does the Commissioner's waiver of requirements relating to sequences as discussed in 1192 O.G. 68 (November 19, 1996) apply given that the instant application is a national phase application.

Other than reliance on the "Examination of Patent Applications Containing Nucleotide Sequences" (1192 O.G. 68), the Office has made no showing that there is lack of unity between the sequences which Applicant is now being required to elect for purposes of restriction and not as species. As an aside, the text quoted on page 3 of the Office Action says that the Commissioner would allow a reasonable number of such nucleotide sequences to be claimed in a single invention. Applicant notes that the Commissioner did *not* limit the number to one.

The Office specifically requests Applicant to elect a single sequence for examination as regards the external trimerisation motif sequence from SEQ ID NOs 1-2, a single survival sequence from SEQ ID NOS: 10-12, and a single linker sequence from SE ID NOs: 3-8. See page 3, Office Action.

M.P.E.P. § 803.02 cites the decisions of *In re Weber* and *In re Hamisch* in acknowledging that it is improper for the U.S. Patent and Trademark Office to refuse to examine that which applicants regard as their invention unless the subject matter lacks unity of invention. *In re Weber*, 198 U.S.P.Q. 328 (C.C.P.A. 1978); *In re Harnisch*, 206 U.S.P.Q. 300 (C.C.P.A. 1980).

The Court of Customs and Patent Appeals (C.C.P.A.) in *Weber* held that an applicant is entitled to claim his invention with the limitations he regards as necessary to circumscribed that invention within the requirements of 35 U.S.C. § 112. *In re Weber* at 331. The Court in *In re Harnisch* extended the findings of *Weber* to hold that a determination of propriety of a Markush type claim is based on a unity of invention standard. *Harnish*, at 305. Unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility. See M.P.E.P. § 803.02. Alternatively stated, a Markush grouping is proper when the substances have "a community of chemical or physical characteristics" which justify their inclusion in a common group and that such inclusion is not repugnant to principles of scientific classification. See, e.g., *Harnish* at 305; *In re Jones*, 74 U.S.P.Q 149, 151 (C.C.P.A. 1947).

In the present case, the sequences are grouped into amino acid linker motifs (SEQ ID NOS: 3-8) as set forth for example in Claim 10, an external trimerisation motif (SEQ ID NO: 1-2), and a single survival sequence (SEQ ID NOS: 10-12). The grouped members of these three groups thus share at least one common utility. Therefore, amongst the groups, there is unity of invention in the instant application according to Markush practice.

Election between the sequences of any one group of sequences is counter to a core reason of justice underlying the findings of the court in *Weber*. In their decision, the court expressed concern that the applicants would be denied the right to ever claim the entire invention if a claim reciting a Markush group were divided across multiple applications. *Weber* at 331-2. If the present Restriction Requirement between the sequences of the three groups is maintained, Applicant would be denied the right to ever claim the entire invention if a claim reciting a Markush group were divided across multiple applications. *Weber*, at 331-332. If the present Restriction Requirement between the groups is not withdrawn, Applicants will never be able to have their invention fully examined on the merits as they have claimed it. Maintaining the present Restriction Requirement on procedural grounds

would raise form over substance of the invention. Such a result is clearly contrary to the decision of the court in *Weber*, and therefore, is improper. *Weber* at 331-2. Thus, restriction of the sequences versus election of a species is improper. Therefore, Applicants respectfully request that the Restriction Requirement, at least, be modified to treat Applicant's election of SEQ ID NO: 12 as a provisional election for search purposes only as set forth in MPEP § 803.02. If the species is found allowable, the elected claims of Group I should be examined with regard to the additional members of the Markush group, *i.e.*, SEQ ID NOS: 10 and 11. The election of SEQ ID NO: 12 is made *with traverse*.

Finally, Applicant notes from a public policy perspective that requiring divisional applications for every sequence placed an undue burden on the public, is counter to the policy of the M.P.E.P., is wasteful of Applicant's resources, and is wasteful of Patent Office resources. It causes a redundancy in formalities raised by requiring multiple applications; it forces the public to search multiple patents and applications to determine the metes and bounds of patent protection that have been granted on the disclosed subject matter; it is burdensome to search for the Patent Office; and from an abstract point for litigation or interference practice, requiring multiple divisional applications based on this form over substance requirement forces an inordinate expenditure of financial resources by the Patent Office and by Applicants/Patentees. Thus, to impose such a burden runs counter to the Constitutional purpose of advancing the useful arts.

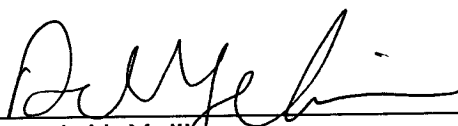
For at least these reasons Applicant requests reconsideration of the restriction with respect to the election of a single sequence. Applicant respectfully requests that a species from each of the three groups be provisionally elected for search purposes alone (or at the very least a species from one of the groups). To maintain a restriction where Applicant must elect a single sequence runs counter to *In re Harnisch* and *In re Weber*. The case law has not been overturned and cannot be altered by the Commissioner's action as set forth in the Official Gazette.

Applicant has no intention of abandoning any non-elected subject matter and expressly reserves the right to file one or more continuation and/or divisional applications directed to the non-elected subject matter.

Applicant earnestly solicits favorable consideration of the above response and early passage to issue the present application. The Examiner is invited to contact the undersigned at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted,
BURNS, DOANE, SWECKER & MATHIS, L.L.P.

Date: November 17, 2004

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